

Exhibit J



Single-use plaque removal efficacy of three power toothbrushes

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KEYWORDS

Oscillating/pulsating
toothbrush;
High-frequency
toothbrush;
Plaque removal;
Plaque Index

Summary Objectives. To compare the safety and plaque removal efficacy of two oscillating/rotating/pulsating toothbrushes (Oral-B ProfessionalCare™ 7000 [PC 7000] and Oral-B 3D Excel [3DE]) and a high-frequency toothbrush (Sonicare® Advance, Philips Oral Healthcare; SA) in a single-use, examiner-blind, three period crossover study.

Methods. After refraining from all oral hygiene procedures for 23-25 hours, subjects received an oral tissue examination and those with pre-brushing whole mouth mean plaque scores ≥ 0.6 based on the Rustogi et al. Modified Navy Plaque Index were randomly assigned to treatment sequence. After brushing with the assigned toothbrush and a commercially available dentifrice for 2 minutes, oral tissues were then re-examined and post-brushing plaque scores recorded. Following a brief washout period between two additional visits, the above procedures were repeated with the two alternate toothbrushes. One examiner, blinded to the treatment sequence, performed all clinical measurements.

Results. A total of 79 subjects (28 males and 51 females) were enrolled and completed the study. Each toothbrush was found to be safe and significantly reduced plaque levels after a single brushing. The PC 7000 and 3DE were equally more effective in plaque removal than the SA, at all tooth areas, reducing plaque by 59.0%, 59.7% and 51.8%, respectively on whole mouth surfaces, and by 67.5%, 67.8% and 59.4%, respectively on approximal surfaces.

Conclusions. The action of the oscillating/rotating/pulsating toothbrushes (Oral-B ProfessionalCare 7000 and Oral-B 3D Excel) was more effective in plaque removal than the high-frequency toothbrush (Sonicare Advance).

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Introduction

Maintenance of oral health is underpinned by effective

plaque control^{1,2}. Numerous manual and electric-powered toothbrushes are available to assist consumers in their oral hygiene efforts. While manual toothbrushes rely on the user to generate and direct brush head motion in order to remove plaque from tooth surfaces, powered toothbrushes have electrically driven brush heads to confer a reliable brushing technique and rely only on the user to guide the brush filaments across the dentition.

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Even though an ever growing body of research-based evidence demonstrates some powered toothbrushes deliver improved plaque removal over manual toothbrushes, a recent independent analysis has indicated not all are consistently superior to manual brushing and concluded only those with an oscillating/rotating action provide consistent benefits in the reduction of plaque and gingivitis³. Both short- and long-term clinical studies of the Oral-B range of oscillating/rotating toothbrushes have repeatedly shown their greater ability to remove plaque and maintain gingival condition compared to manual brushing⁴⁻⁶.

Evolution of power toothbrush technology has seen development of brushes with distinct brush head designs, brush stroke frequency and action, which raises questions about their relative effectiveness in plaque removal. The most recent model in the oscillating/rotating/pulsating range of power toothbrushes, now known as the Oral-B ProfessionalCare™ Series, is the ProfessionalCare 7000 (PC 7000; Oral-B Laboratories, Boston, MA, USA), which has been developed as an upgrade to the 3D Excel (3DE). While both powered toothbrushes incorporate a small round brush head with a pulsating frequency of 340 Hz, the oscillating action in the PC 7000 has been increased from 63 Hz (7600 oscillation brush movements per minute) to 73 Hz (8800 oscillation brush movements per minute)⁷. Alternatively, the Sonicare® Advance toothbrush (SA; Philips Oral Healthcare, Snoqualmie, WA, USA) has a conventionally shaped brush head that moves from side to side at a high frequency of 260 Hz (approximately 31000 brush strokes per minute)⁸.

The objective of the present study was to evaluate and compare the safety and plaque removal efficacy of two oscillating/rotating toothbrushes (the PC 7000 and the established 3DE) and a high-frequency toothbrush (SA) after single brushing. The Rustogi et al. Modified Navy Plaque Index (RMNPI) was applied to assess the presence of plaque, since this index emphasises scoring of interproximal and gumline regions, where plaque is most likely to accumulate^{9,10}.

Materials and Methods

Subjects

Healthy adults aged between 18 and 70 years who were current users of power toothbrushes were recruited from the general population of a large metropolitan area. In addition, subjects were required to have a minimum of 18 scorable teeth (not including 3rd molars, teeth with orthodontic appliances, bridges, crowns or implants). Subjects refrained from all oral hygiene procedures, including the use of interdental cleaning products, chewing gums and mouth rinses for 23-25 hours and from eating, drinking or smoking for 4 hours prior to their clinic visits. Eligible participants had a whole mouth pre-brushing plaque of ≥ 0.6 based on the RMNPI (Fig. 1)⁹. Subjects were excluded from the study for any of the following reasons: evidence of neglected dental health, any physical limitation or restriction that might preclude normal oral hygiene

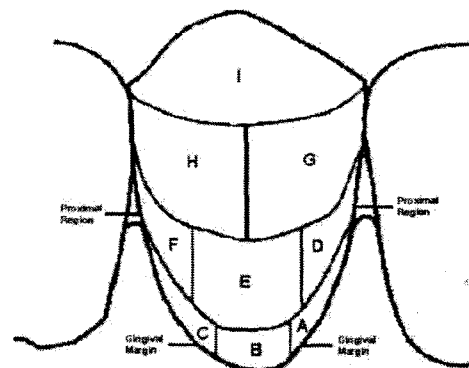


Figure 1. Rustogi et al. Modified Navy Plaque Index⁹. Disclosed plaque is scored in each tooth area as present (scored as 1) or absent (scored as 0) and recorded for both buccal and lingual surfaces. Tooth area plaque scores are grouped and designated as: Whole mouth = Areas A, B, C, D, E, F, G, H and I; Marginal (gumline) = Areas A, B and C only; Approximal = Areas D and F only.

procedures, presence of major hard or soft tissue lesions at the baseline examination, use of antibiotics or anti-inflammatory medications for 3 consecutive days or more within the previous 28 days, and any medical condition with a requirement of prophylactic antibiotics before dental treatment. The study protocol was approved by an independent Institutional Review Board before initiation. All subjects gave signed informed consent and completed a medical history form before study entry.

Study design

This study had a randomised, examiner-blind, three-arm, single-use crossover design. Safety of the PC 7000 brush was evaluated further in a subset of subjects over a 30-day period of twice-daily usage. At the initial visit, subjects who had refrained from all oral hygiene procedures in the previous 23-25 hours and eating, drinking or smoking in the previous 4 hours received an oral tissue examination and pre-existing levels of plaque were determined to establish if they met the inclusion criteria. Soft and hard oral tissues examined were lips, tongue, gingivae, sublingual area, inner surfaces of cheeks, mucobuccal folds, hard and soft palate, and pharyngeal area. Assessments included colour, texture, soft tissue abrasion and any irregularities. Gross effects on hard tissues and dental restorations were noted. Plaque was evaluated after disclosing the teeth with Chrom-O-Red (Germiphene Corp., Brantford, Ontario, Canada) using the RMNPI, which divides each of the buccal and lingual surfaces of all scorable teeth into nine areas and scores plaque 0 or 1 (0 = absent, 1 = present).

Qualified subjects were randomised into one of six treatment sequence groups. A set of two Latin squares was used to form the randomisation to ensure the design was balanced for first-order carryover effects since each treatment would precede the other two treatments exactly twice. Subjects brushed with their assigned toothbrush, the PC 7000, 3DE or the SA toothbrush, in accordance with instructions provided by the manufacturer. Sufficient time was allowed for

subjects to understand and ask questions about the brushing technique. A commercially available fluoride dentifrice (Crest Cavity Protection toothpaste, Procter & Gamble Company, Cincinnati, OH, USA), sufficient to cover the area of the toothbrush filaments, was applied by the brushing supervisor. Subjects brushed for 2 minutes, timed, in the absence of mirrors, and out of view of the clinical examiner. Oral tissues were then re-examined and, after disclosure, post-brushing plaque scores were recorded.

Subjects returned to their usual method of oral hygiene for a brief washout period (minimum 4 days) between two additional visits when the above procedures were repeated with the two alternate toothbrushes. At each visit, the medical history, general health status and current medication usage were reviewed. All clinical evaluations were performed by the same examiner who was blind to the test products and treatment group assignments. The examiner was familiar with the indices used and had been calibrated for intra-examiner reproducibility. Any abnormal findings and any adverse events reported were recorded.

Those subjects continuing in the safety phase of the study were provided with their previously used PC 7000 toothbrush and were instructed to use the test brush at home twice daily for a 30-day period. Each subject recorded their brushing times and any comments on a brushing diary sheet. All subjects abstained from the use of interdental cleaning products, chewing gums and mouthrinses over the 30-day period and returned to the test facility for an assessment of oral soft and hard tissues.

Toothbrush design

Both the Oral-B PC 7000 and 3DE toothbrushes have a round brush head that features an oscillating/rotating/pulsating action (Fig. 2). In comparison with the

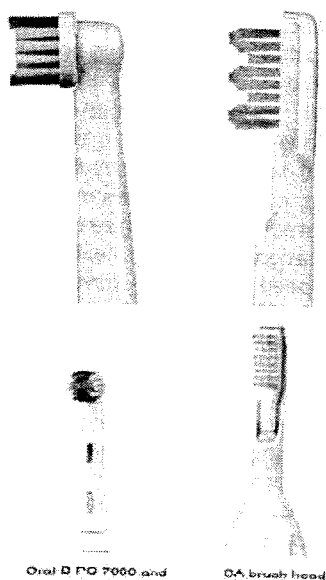


Figure 2. Brush heads.

3DE model, the oscillating speed of the PC 7000 has been increased from 63 Hz to a frequency of 73 Hz while the pulsating frequency remains the same at 340 Hz. Both brushes have a pressure control system that limits brushing force by switching off the vibratory action at a preset pressure. The SA toothbrush has a side-to-side motion, operates at a frequency of 260 Hz and has a conventionally shaped brush head (Fig. 2). The Easy-Start feature was deactivated prior to use and the brush was used at the normal setting as recommended by the manufacturer.

Statistical analysis

Variability estimates and power curves from previous studies of this design (data on file, Oral-B Laboratories) were used to determine the number of subjects needed to detect statistically significant treatment differences. Based on these data, assuming $\alpha=0.05$, a sample size of 75 subjects was required to ensure an 80% (power = $1 - \beta$) or greater chance of detecting differences of ≥ 0.02 whole mouth RMNPI units. The baseline distribution for age was analysed for differences between treatment sequence groups using an analysis of variance (ANOVA) and for gender using a chi-square test for homogeneity. Baseline RMNPI data were analysed for comparability between treatment groups using an ANOVA at each visit. Changes within each treatment group were evaluated using a paired *t*-test. Appropriate tests between treatment sequences were conducted to determine the presence of carryover effects in the 3-arm crossover design. Pre- to post-use differences between treatment groups in the RMNPI score for whole mouth (primary endpoint), marginal and approximal surfaces (secondary endpoints) were analysed using an ANOVA model that adjusted for period and residual (carryover) effects. The least-significant-difference method was used for pairwise comparisons between groups. All hypothesis tests were conducted at the two-sided $\alpha=0.05$ level of significance.

Results

Study population

A total of 82 subjects, from the general population of a large metropolitan area, were scheduled; 3 subjects did not appear for enrolment so that 79 subjects were enrolled, provided evaluable data and completed the study. Evaluable subjects included 28 males and 51 females of mean age 36.3 years (range, 18-53 years). There was no significant difference between treatment sequence groups for gender, or age, or whole mouth RMNPI scores in each of the treatment groups at each visit (Tables 1 and 2). A subset of 28 subjects gave additional safety data after twice-daily home use of the PC 7000 over 30 days.

Table 1 Subject demographics

Treatment sequence	Male/female	Age (mean±SD, yrs)
3DE/SA/PC 7000	4/9	37.1±6.7
PC 7000/3DE/SA	4/10	33.9±12.2
SA/PC 7000/3DE	4/9	36.7±10.7
PC 7000/SA/3DE	4/9	37.8±7.0
3DE/PC 7000/SA	7/6	36.0±9.1
SA/3DE/PC 7000	5/8	36.6±10.3
P-value	0.7557	0.9263

Table 2 Pre-brushing whole mouth RMNPI scores (mean±SD)

Toothbrush	Visit 1	Visit 2	Visit 3
PC 7000	0.64±0.03	0.63±0.03	0.64±0.03
SA	0.63±0.02	0.64±0.04	0.63±0.03
3DE	0.63±0.04	0.64±0.03	0.64±0.04
P-value	0.1666	0.4320	0.7706

Efficacy

A summary of the pre- and post-brushing (pooled across visits) plaque data for all surfaces is shown in Table 3. Each toothbrush was effective in removing plaque from all tooth surfaces after a single use. The PC 7000, 3DE and SA toothbrushes demonstrated significant reductions in mean plaque scores from pre-brushing to post-brushing levels for whole mouth, marginal and approximal surfaces ($P=0.0001$ for all pre- to post-brushing changes). Analysis of carryover

Table 3 Pre- and Post-brushing RMNPI scores and plaque reduction (mean±SD)

Toothbrush	Pre-brushing	Post-brushing	Plaque reduction*
Whole mouth			
PC 7000	0.64±0.03	0.26±0.08	0.38±0.06
3DE	0.63±0.03	0.26±0.07	0.38±0.06
SA	0.64±0.03	0.31±0.09	0.33±0.07
*PC 7000 vs. 3DE, $P=0.678$; PC 7000 vs. SA, $P=0.0001$; 3DE vs. SA, $P=0.0001$			
Gingival margin			
PC 7000	1.00±0.00	0.50±0.12	0.50±0.12
3DE	1.00±0.00	0.49±0.11	0.51±0.11
SA	1.00±0.00	0.56±0.13	0.44±0.13
*PC 7000 vs. 3DE, $P=0.101$; PC 7000 vs. SA, $P=0.0001$; 3DE vs. SA, $P=0.0001$			
Approximal			
PC 7000	1.00±0.00	0.33±0.12	0.68±0.12
3DE	1.00±0.00	0.32±0.11	0.68±0.11
SA	1.00±0.00	0.41±0.15	0.59±0.15
*PC 7000 vs. 3DE, $P=0.919$; PC 7000 vs. SA, $P=0.0001$; 3DE vs. SA, $P=0.0001$			

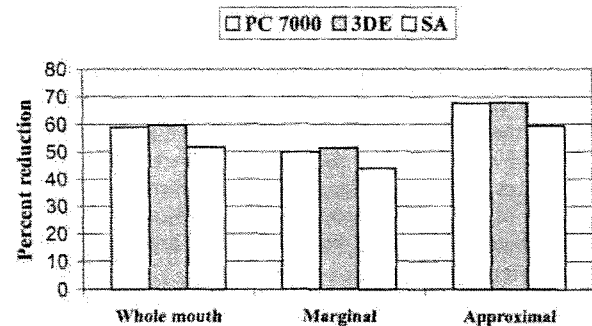


Figure 3. Plaque removal efficacy of the PC 7000, 3DE and SA toothbrushes after single-use brushing.

effects revealed that the effect of SA on subsequent treatment was greater than the effect of PC 7000 or 3DE on subsequent treatments for whole mouth ($P=0.0304$) and marginal surface ($P=0.0239$), and approached significance for approximal surface ($P=0.0554$). These differences were accounted for by including the residual effects in the ANOVA model. ANOVA comparisons between treatment groups revealed a significant treatment difference ($P=0.0001$) for all sites. Both the PC 7000 and 3DE toothbrushes had significantly greater efficacy ($P=0.0001$) than the SA in plaque removal for all sites, but no significant difference was found between the PC 7000 and 3DE brushes (Table 3). The percentage reductions in plaque for the whole mouth, marginal and approximal surfaces were 59.0%, 50.0% and 67.5%, respectively with the PC 7000 brush; 59.7%, 51.4% and 67.8%, respectively with the 3DE brush; and 51.8%, 43.9% and 59.4%, respectively with the SA toothbrush (Fig. 3).

Safety

No adverse events were reported during the study. One abnormality on the tongue was noted in one subject before brushing at each visit. No post-brushing changes in oral tissues or restorations were reported or observed with any toothbrush after single-use. A comparison of oral hard and soft tissue conditions present before and after 30 days of use with the PC 7000 toothbrush revealed no changes.

Discussion

Numerous powered toothbrushes are currently marketed, displaying variations in brush head design, filament pattern and speed of motion developed to improve plaque removal efficacy, especially from interproximal regions where manual toothbrushing is least effective¹¹. Both types of powered toothbrushes used in our study, the Oral-B oscillating/rotating brush and the high-frequency Sonicare brush, have shown advantages over manual brushing in the removal of plaque, most notably from interproximal regions¹². The introduction of newer models, such as the Oral-B ProfessionalCare 7000, highlights the need for comparative studies to investigate their plaque removal efficacy relative to other established powered toothbrushes with differences in design and mode of action.

Results from this single-use brushing study demonstrate that all three toothbrushes effectively removed plaque from whole mouth, marginal and approximal surfaces, but significantly more plaque was removed with the Oral-B 3DE and PC 7000 toothbrushes than the Sonicare toothbrush. No significant difference was found between the two Oral-B brushes in their plaque removal ability. Importantly, the clinical advantage in favour of the oscillating/rotating/pulsating toothbrushes was evident not only on whole mouth surfaces, but also on difficult-to-access approximal surfaces. Previous clinical studies of the Oral-B oscillating/rotating brushes versus the high-frequency Sonicare toothbrush conducted in normal subject populations have found at least equivalent, if not superior, plaque removal efficacy with the Oral-B powered toothbrush¹³⁻¹⁷. Interestingly, one study used the same Modified Navy Index¹⁴ applied in the present study, which assesses plaque on nine areas of each tooth, placing an emphasis on gumline and approximal sites. Again significantly greater plaque reduction from approximal surfaces was found with the Oral-B oscillating/rotating brush than the high-frequency Sonicare brush.

In-vitro investigations have purported to evaluate plaque removal efficacy of powered toothbrushes as would occur *in-vivo*¹⁸, and although *in-vitro* studies provide a useful development tool their findings do not necessarily reflect clinical performance. The effectiveness of toothbrushes to remove plaque must ultimately be investigated in a clinical situation and well-designed studies can distinguish clinical differences between toothbrushes by controlling factors such as duration and frequency of brushing, and the methods used to evaluate plaque. In order to ensure reliability of the results found in the present study, the following methodology was employed: the crossover design allowed all subjects to use each brush; the abstention period from toothbrushing was defined at 23-25 hours to minimise inherent variation in the rate of plaque formation¹⁹; toothbrushing methods were as described by the manufacturers and timed at 2 minutes; and the same clinical examiner familiar with the RANPI evaluated plaque pre- and post-brushing, but was blind to treatment assignment. Although single-use studies provide a direct assessment of the plaque removal ability of a toothbrush, longer-term studies are required to determine if benefits in plaque removal translate into improvements in gingival health.

Conclusion

Both the oscillating/rotating/pulsating toothbrushes were equally more effective in plaque removal than the high-frequency toothbrush after a single use. This advantage was evident not only on whole mouth surfaces, but also on approximal surfaces, which are difficult to access and clean effectively.

Acknowledgements

The authors would like to thank Melynda Hazelwood,

STATKING Consulting, Fairfield, OH, USA for statistical analysis and Dr Jane Mitchell, MWS, Staffordshire, UK for preparation of this manuscript.

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